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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,276

03/10/2008

Erich Wanker

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11/22/2010

PILLSBURY WINTHROP SHAW PITTMAN LLP

ATTENTION: DOCKETING DEPARTMENT

P.O BOX 10500

McLean, VA 22102

EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,276	<b>Applicant(s)</b> WANKER ET AL.	
	<b>Examiner</b> JAGADISHWAR R. SAMALA	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 16-22 is/are pending in the application.  
     4a) Of the above claim(s) 2-14, 16, 20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 17-19 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/10/2006</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### **Election/Restrictions**

Applicant's election with traverse of Group VIII, claims 1 (in part) and 17-21 in the reply filed on 10/15/2010 is acknowledged. The traversal is on the ground(s) that compound V-2 (claim 1) has structural similarities with the elected species of compound V-1. This is found persuasive and therefore, compound V-2 is rejoined for examination.

The requirement is still deemed proper and is therefore made FINAL.

- Claim 15 has been cancelled.
- Claims 1-14 and 16-22 are pending in the instant application.
- Claims 2-14, 16, 20 and 22 from above are withdrawn from consideration as non-elected species.

### **Information Disclosure Statement**

The information disclosure statement (IDS) submitted on 08/10/2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### **Drawings**

The drawings were received on 08/10/2006. These drawings are acknowledged.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 17-19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi et al (US 2002/0086067).

Claims are drawn to a method for the treatment or diagnosis of neurodegenerative disorder or amyloid disease comprising administering a pharmaceutical or diagnostic composition comprising (-) epigallocatechin gallate or gallic acid.

Choi teaches a method of treatment, or management of an amyloidosis in a mammalian subject, comprising the step of administering a therapeutic amount of green tea derivatives such as (-) epigallocatechin gallate or gallic acid (abstract and claim 1). The treatment of amyloidosis is selected from the group of amyloidosis consisting of Alzheimer's disease, the amyloidosis associated with the prion diseases including Creutzfeldt-Jakob disease, Gerstmann-Sträussler syndrome, the amyloidosis associated with long-term hemodialysis and carpal tunnel syndrome... (claim 2). The claims are therefore anticipated by Choi's patent.

Claims 1, 17-19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Castillo et al (WO-03/013442 herein after '442).

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Claims are drawn to a method for the treatment or diagnosis of neurodegenerative disorder or amyloid disease comprising administering a pharmaceutical or diagnostic composition comprising (-) epigallocatechin gallate or gallic acid.

Castillo teaches a method of treating an amyloid disease comprising administering to the mammal a therapeutically effective amount of catechin derivatives such as (-) epigallocatechin gallate or gallic acid and pharmaceutically acceptable excipient (abstract and page 6 lines 10-16). The treatment of amyloid disease is selected from group consisting of Alzheimer's disease, systemic AA amyloidosis, the amyloidosis associated with the prion diseases including Creutzfeldt-Jakob disease, Gerstmann-Sträussler syndrome, the amyloidosis associated with long-term hemodialysis and carpal tunnel syndrome... (claim 3). The claims are therefore anticipated by '442 patent.

### **Conclusion**

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./  
Examiner, Art Unit 1618

/Jake M. Vu/  
Primary Examiner, Art Unit 1618